

Appl. No 10/789,525
Docket No. 9192ML
Reply to Office Action of October 17, 2007
Customer No. 27,752

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REMARKS

Claim Status

Upon entry of the claim amendments and cancellations herein, Claims 1, 2, 4, 5, 11, 14, 15, 21, and 24 will be pending. Claims 3, 6 – 10, 12, 13, 16 – 20, 22, and 23 have been canceled without prejudice. Claim 24 has been withdrawn.

The Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1 and 2 have been rejected under 35 U.S.C. § 112, first paragraph, based on use of the terms “pharmaceutical active” and “nutrient” without further specificity. Claim has been amended to recite the “pharmaceutical active” as a bisphosphonate and the “nutrient” as selected from calcium, vitamin D, calcium and vitamin D, and a combined unit dose of calcium and vitamin D. Dependent Claim 2 is affected by this amendment. As such, the rejection is now moot and should be withdrawn.

The Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 2 has been rejected under 35 U.S.C. § 112, second paragraph, based on use of the term “the memory”. Claim 2 has been amended to delete the word “the” and, as such, the rejection is now moot and should be withdrawn.

The Rejection Under 35 U.S.C. § 103(a)

Claims 1 – 23 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,366,965 (“Strein”).

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From the outset, Strein is distinguished from the claims of the present invention based on the cyclical nature of bisphosphonate dosing relative to the continuous dosing recited in Claim 1 of the present invention and its dependents. Strein discloses a dosing regimen containing an inhibiting period and a rest period; the inhibiting period contains at least two intermittent periods (see Strein, Column 3, lines 65 – 69). The bisphosphonate is dosed during the on only one day of the intermittent period (see Strein, Column 4, lines 4 – 6). The rest period lasts for 20 – 120 days, more preferably 50 – 100 days, more preferably about 60 – 84 days, and most preferable about 75 – 80 days (see Strein, Column 4, lines 10 – 12).

Moreover, it is only during the rest period, again lasting for 20 – 120 days, that Strein suggests use of a nutrient such as calcium or vitamin D. This administration is after the inhibiting period, during which bisphosphonate is dosed only one day of each intermittent period. Strein only discloses administration of a placebo during the remaining days of the inhibiting period.

Thus, Strein discloses a cyclical regimen in which a bisphosphonate is dosed on at least two days during an inhibiting period, wherein those two days are separating by dosing with or without a nutrient during the remaining days of the inhibiting period; after that is the rest period in which no bisphosphonate is dosed. As such there are long periods within the inhibiting period that no bisphosphonate is dosed, followed by another long period over the entire rest period (20 – 120 days) in which no bisphosphonate is dosed.

In contrast to Strein, the claims of the present invention are directed to kits in which bisphosphonate is dosed in accordance with a continuous, *not cyclical*, regimen. See section (a) of Claim 1 which directs administration of bisphosphonate continuously. Moreover, Applicants have amended the claims herein to recite a more specific regimen in which the kit is arranged for once-weekly dosing of the bisphosphonate by providing 4 unit doses of the bisphosphonate and 24 unit doses of the nutrient.

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In view of the foregoing, Applicants assert that the claims as amended herein would not have been obvious in view of Strein and the rejection should be withdrawn.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from Strein. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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